Commission Regulation (EU) No 630/2013 of 28 June 2013 amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (Text with EEA relevance)

COMMISSION REGULATION (EU) No 630/2013

of 28 June 2013

amending the Annexes to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies[(1)], and in particular the first paragraph of Article 23 thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in bovine, ovine and caprine animals. It applies to the production and placing on the market of live animals and products of animal origin and in certain specific cases to exports thereof.

(2) On 19 January 2011, the European Food Safety Authority (EFSA) published a joint opinion prepared with the European Centre for Disease Prevention and Control (ECDC) on any possible epidemiological or molecular association between TSEs in animals and humans ('the joint EFSA and ECDC Opinion')[(2)]. In the joint EFSA and ECDC opinion, the EFSA and ECDC confirmed the identification of atypical forms of bovine spongiform encephalopathy (BSE) in cattle and made the distinction between classical BSE, L-type atypical BSE and H-type atypical BSE. It is therefore appropriate to insert definitions for classical BSE cases and atypical BSE cases in Annex I to Regulation (EC) No 999/2001.

(3) Part I of Chapter A of Annex III to Regulation (EC) No 999/2001 lays down rules for monitoring BSE in bovine animals slaughtered for human consumption. It refers to animals slaughtered in accordance with 'special emergency slaughter' as defined in Article 2(n) of Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marketing of fresh meat[(3)]. That Directive has since been repealed by Directive 2004/41/EC of the European Parliament and of the Council[(4)]. This has led to legal uncertainty and caused reduced testing in animals that should have been tested. It is therefore necessary to clearly define emergency slaughter in the framework

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) No 630/2013. (See end of Document for details)*

of the rules for monitoring BSE in bovine animals slaughtered for human consumption in Annex III to Regulation (EC) No 999/2001.

(4) Part II of Chapter A of Annex III to Regulation (EC) No 999/2001 lays down rules for monitoring in ovine and caprine animals. The annual reports carried out by the Member States on the monitoring and testing of ruminants for the presence of Transmissible Spongiform Encephalopathy (TSE) in the Union have shown in recent years that the testing of ovine and caprine animals not slaughtered for human consumption is usually more efficient to identify cases of TSE than the testing of animals slaughtered for human consumption. More flexibility should therefore be given to the Member States to focus a larger part of the limited number of tests required by that Annex in the subpopulations where there is a greater chance to identify such cases.

(5) Annex VII to Regulation (EC) No 999/2001 lays down the eradication measures to be carried out following the confirmation of the presence of TSE in bovine, ovine and caprine animals and the minimum requirements for breeding programmes for resistance to TSEs in sheep. That Annex has been amended several times, including by Commission Regulations (EC) No 727/2007[(5)] and (EC) No 746/2008[(6)].

(6) On 17 July 2007, in Case T-257/07, France brought an action against the Commission before the General Court, applying for the suspension of the operation of point (3) of the Annex to Regulation (EC) No 727/2007 insofar as it introduces point 2.3(b)(iii), point 2.3(d) and point 4 into Chapter A of Annex VII to Regulation (EC) No 999/2001, or alternatively the entire annulment of that Regulation. According to France, those points would authorise less restrictive measures of surveillance and eradication than those earlier prescribed for sheep and goats. In its Order of 28 September 2007[(7)], the Court suspended the application of those provisions until judgment would be given in the main action.

(7) The Commission subsequently asked the EFSA to assist it in clarifying the main premises on which Regulation (EC) No 727/2007 was based. In view of the EFSA clarifications, Regulation (EC) No 999/2001 was amended by Regulation (EC) No 746/2008, which reinstated provisions the application of which had been suspended by the General Court. In its Order of 30 October 2008[(8)], the General Court suspended the application of point 2.3(b)(iii), point 2.3(d) and point 4 of Chapter A of Annex VII to Regulation (EC) No 999/2001, as amended by Regulation (EC) No 746/2008, until judgment would be given in the main action in Case T-257/07.

(8) In its judgment of 9 September 2011 in Case T-257/07[(9)], the General Court dismissed the application by France for the annulment of Regulation (EC) No 746/2008, and lifted the suspension of the application of those provisions of Chapter A of Annex VII to Regulation (EC) No 999/2001.

(9) On 28 November 2011, in Case C-601/11 P[(10)], an appeal was brought by France against the judgment of the General court in Case T-257/07, requesting the Court to set aside the judgment of the General Court in Case T-257/07 and to give final judgment in the dispute by annulling Regulation (EC) No 746/2008 or to refer the case back to the General Court.

(10) It is appropriate to clarify the very complex construct of management options and derogations for the control and eradication of classical scrapie in ovine and caprine animals set out in Annex VII to Regulation (EC) No 999/2001. Annex VII should only provide for three options in infected flocks or herds of ovine and caprine animals, namely: option 1 for the elimination of all animals; option 2 for the elimination of the susceptible animals only; and option 3 for no mandatory elimination of animals.

(11) The measures to be applied in each of those three options should be re-drafted in order to facilitate comparison between the options and improve awareness of the consequences for the individual holding. As option 1 and option 2 include stringent eradication measures which improve disease control, the post-eradication measures enforced under option 1 and option 2 should be more flexible than under option 3.

(12) It is necessary to clarify the conditions under which the elimination measures set out in option 2 may be delayed. It is appropriate to allow for a short term delay not exceeding three months linked to lambing season considerations. However, a long term delay can only be justified by the need of additional time to increase the level of genetic resistance to classical scrapie in a holding. Since genetic resistance to classical scrapie has so far been proven only in ovine animals, the long term delay should not be permitted for herds comprising only caprine animals. When permitted, it should be limited to a period of three years under certain conditions.

(13) Where classical scrapie is confirmed in holdings keeping a local ovine breed in danger of being lost to farming, the post-eradication measures laid down in Annex VII to Regulation (EC) No 999/2001 should take into consideration the difficulty of introducing and using only resistant ovine animals or ovine germinal products of the same endangered breed. In this particular case, Member States should be permitted to apply more flexible rules regarding the genotype of breeders and germinal products introduced and used in the holdings.

(14) The joint EFSA and ECDC Opinion suggests that atypical scrapie could be little or not contagious at all. That finding mainly relies on the lack of statistical difference of the observed Atypical/Nor98 frequencies between the general population and the flocks where a positive case had been identified. Therefore, restriction measures on the movement of ovine and caprine animals where a case of atypical scrapie has been confirmed are no longer justified. Increased surveillance in those flocks or herds should, however, be maintained in order to gather more scientific data on atypical scrapie. This amendment to Annex VII to Regulation (EC) No 999/2001 is in line with the future policy options envisaged by paragraph 2.4.3 of the Communication from the Commission to the European Parliament and the Council — The TSE Road map 2 — A Strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015[(11)].

(15) The participation in breeding programmes has been so far limited to ovine flocks of high genetic merit. Where they have been applied, the breeding programmes have been effective in increasing the resistance to classical scrapie in the high genetic merit sheep population. But the diffusion in the ordinary production population of the hereditary factor (allele) carrying the resistance appears to have been limited so far. Chapter C of Annex VII to Regulation (EC) No 999/2001 should allow the genotyping of

the breeding rams of flocks not participating in the breeding programme in order to facilitate a broader diffusion of the resistance factor to classical scrapie in the production population.

(16) Chapter A of Annex VIII to Regulation (EC) No 999/2001 lays down rules governing intra-Union trade in live animals, semen and embryos. As referred to in recital 14, the joint EFSA and ECDC Opinion suggests that atypical scrapie could be little or not contagious at all. The lifting of all restriction measures on the movement of ovine and caprine animals where a case of atypical scrapie has been confirmed should therefore apply to intra-Union trade. This position is also supported by the fact that the Terrestrial Animal Health Code, as voted in 2010 at the 78th General Session of the World Organisation for Animal Health (OIE), does not recommend any trade restriction with regards to atypical scrapie.

(17) The rules set out in Annex VIII to Regulation (EC) No 999/2001 relating to intra-Union trade in ovine and caprine animals and their semen and embryos should be made as consistent as possible with the OIE standards, so that they do not preclude Member States with an approved national control programme for classical scrapie from claiming the country freedom status for classical scrapie according to the conditions laid out in the OIE code. The amended intra-Union trade provisions should however not adversely impact existing intra-Union trade flows among Member States where no national control programme for classical scrapie has been approved.

(18) For that purpose, and as proposed in paragraph 2.4.3 of the TSE Roadmap 2, a framework enabling the Member States to establish an official scheme for the recognition of classical scrapie status in holdings should be set out in Annex VIII to Regulation (EC) No 999/2001. The possibility for a holding to engage in intra-Union trade of ovine and caprine animals, with regards to classical scrapie, should be determined by its classical scrapie status.

(19) A two tiered system for classical scrapie status in holdings should be established in Annex VIII to Regulation (EC) No 999/2001. A negligible risk status, equivalent in technical terms to the scrapie free status in a holding, as laid down in Article 14.9.5. of the OIE Terrestrial Animal Health code and based on compliance with the full list of the OIE requirements for at least seven years (in line with the rule laid down in article 6a and Annex VII to Regulation (EC) No 999/2001 favouring the development of the resistant genotypes in ovines, the proposal however recognises the ARR/ARR genotype as a valid option), should be required for transporting animals for breeding and rearing to the Member States with an approved national control programme for classical scrapie. Animals for breeding intended to other Member States should only be required to come from holdings with a controlled risk of classical scrapie based on compliance with a shorter list of requirements for at least three years, as is presently the case.

(20) Considering the difficulty to demonstrate freedom in the territory of part of the territory of a Member State for a disease as complex as classical scrapie, which is characterised by a long incubation delay, the absence of any in-vivo diagnostic method and a variable individual susceptibility of the animals depending on their genetic profile, the concept of ‘classical scrapie free Member State’ should be replaced in Annex VIII to Regulation

(EC) No 999/2001 by that of 'Member State or zone of a Member State with a negligible risk of classical scrapie'. The conditions for the recognition of a Member State or zone of a Member State with a negligible risk of classical scrapie should also be updated and largely brought in line with the recommendations laid down in Article 14.9.3 of the OIE Terrestrial Animal Health code.

(21) As Annex VIII to Regulation (EC) No 999/2001 should cover all trade aspects related to classical scrapie, and considering that the proposed creation of an official scheme for the recognition of classical scrapie status in holdings constitutes an appropriate basis for establishing differentiated guarantees for animals to be traded with Member States with an approved national control plan for classical scrapie and with other Member States, that Annex should also include the list of Member States with an approved national control plan for classical scrapie.

(22) Chapter C of Annex IX to Regulation (EC) No 999/2001 lays down rules relating to imports into the Union of products of animal origin from bovine, ovine and caprine animals, in particular gelatine intended for human consumption. Section A of Chapter D of Annex IX to Regulation (EC) No 999/2001 lays down rules related to imports into the Union of animal by-products and derived products from bovine, ovine and caprine origin, in particular gelatine intended to be used as feed ingredient. Since collagen intended to be used for food or feed is produced from the same raw materials as gelatine, import conditions for collagen to be used for food or feed should be aligned with those laid down for gelatine intended for the same usage.

(23) Section B of Chapter D of Annex IX to Regulation (EC) No 999/2001 provides specific attestations which are to accompany imports into the Union of certain animal by-products and derived products of bovine, ovine and caprine origin. Those attestations should be amended in order to also apply to products processed in a third country classified as posing a controlled or undetermined BSE risk and made from mixed material originating from this third country as well as from a third country with a negligible BSE risk. The specific attestation regarding the importation of products containing milk of ovine and caprine origin and intended for feeding farmed animals should also be amended to better reflect the restrictions applicable to intra-Union trade in these products.

(24) Chapters E and H of Annex IX to Regulation (EC) No 999/2001 lay down rules for the importation in the Union of ovine and caprine animals, and ovine and caprine semen and embryos. Those import rules should be updated to reflect the conditions for intra-Union trade laid down in Annex VIII to Regulation (EC) No 999/2001, including the general pre-requisites in terms of monitoring and eradication of classical scrapie laid down in Annexes III and VII to Regulation (EC) No 999/2001, as well as feed ban provisions laid down in Annex IV to Regulation (EC) No 999/2001.

(25) Annex X to Regulation (EC) No 999/2001 lays down the methods of analysis applicable to TSE testing in bovine, ovine and caprine animals. The joint EFSA and ECDC Opinion indicated that the L-type Atypical BSE agent has a significant zoonotic potential (transmission from animals to humans), which appears similar or even higher than that of the Classical BSE agent. L-type and H-type cases of atypical BSE have